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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/684,178 | 10/10/2003 | Gerardo M. Castillo | 17170-004001 | 2631 |
| 20985 | 7590 | 03/29/2005 | EXAMINER | |
| FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081 | | | COVINGTON, RAYMOND K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/684,178

Applicant(s)

CASTILLO ET AL

Examiner

Raymond Covington

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Restriction Request

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 94 and 95, drawn to procyanidin B2 products, classified in class 549, subclass 403, for example.
- II. Claims 1-14, drawn to a process for synthesizing procyanidin B2, classified in class 422, subclass 261, for example.
- III. Claim 15-21, drawn to a method for isolating procyanidin B2 classified in class 549, subclass 403, for example.
- IV. Claims 62-90 and 93 are drawn to the manufacture of a medicament, classified in class 514, subclass 456, for example.
- V. Claims 31-32 and 35-36, drawn to a method of treating Alzheimer's disease , Down's syndrome, dementia pugilistica, multiple system atrophy, inclusion body myositis, hereditary cerebral hemorrhage with amyloidosis of the Dutch type, Nieman-Pick disease type C, cerebral β -amyloid angiopathy, dementia associated with cortical basal degeneration, the amyloidosis of type 2 diabetes, the amyloidosis of chronic inflammation, the amyloidosis of malignancy and Familial Mediterranean Fever, the amyloidosis of multiple myeloma and B-cell dyscrasias, the amyloidosis of the prion diseases,

Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, kuru, scrapie, the amyloidosis associated with carpal tunnel syndrome, senile cardiac amyloidosis, familial amyloidotic polyneuropathy, and the amyloidosis associated with endocrine tumors using procyanidin B2 as described in claim 1, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- VI. Claims 50-51 and 54-55, drawn to a method of treating Alzheimer's disease, Down's syndrome, dementia pugilistica, multiple system atrophy, inclusion body myositis, hereditary cerebral hemorrhage with amyloidosis of the Dutch type, Nieman-Pick disease type C, cerebral β -amyloid angiopathy, dementia associated with cortical basal degeneration, the amyloidosis of type 2 diabetes, the amyloidosis of chronic inflammation, the amyloidosis of malignancy and Familial Mediterranean Fever, the amyloidosis of multiple myeloma and B-cell dyscrasias, the amyloidosis of the prion diseases, Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, kuru, scrapie, the amyloidosis associated with carpal tunnel syndrome, senile cardiac amyloidosis, familial amyloidotic polyneuropathy, and

the amyloidosis associated with endocrine tumors using procyanidin B2 isolated as described in claim 15, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

VII Claims 37 and 56, drawn to a method of treating humans using procyanidin B2 as described in claims 1 and 15, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different

process (MPEP § 806.05(f)). In the instant case the product can be made by another materially different non-synthetic process.

If the compounds of an elected group are found allowable then group II to the extent of the scope of the elected group can be rejoined with the elected group.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by another materially different non-synthetic process.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make other materially products already shown to be a separate and distinct inventions.

If the compounds of an elected group are found allowable then group II to the extent of the scope of the elected group can be rejoined with the elected group.

If the compounds of an elected group are found allowable then group II to the extent of the scope of the elected group can be rejoined with the elected group.

Inventions I and V are unrelated because each one of the said groups are drawn to methods treating different unrelated diseases and conditions using different sets of compounds embraced by different groups already shown to be a separate and distinct inventions.

If the compounds of an elected group are found allowable then group V to the extent of the scope of the elected group can be rejoined with the elected group.

Inventions II-III are unrelated and different inventions since each one of the said groups are drawn to processes using different process steps and a reference anticipating or suggesting a given group cannot be used to reject any of the others under the meaning of 35 USC 102 or 35 USC 103.

Inventions V-VII are unrelated because each one of the said groups are drawn to methods treating different unrelated diseases and condition using different sets of compounds embraced by different groups already shown to be a separate and distinct inventions.

Inventions II or III are unrelated to any one of groups V-VII as they are drawn to unrelated and different inventions since the compounds used in groups V-VII may be synthesized or isolated by processes using different process steps from

groups II and III and a reference anticipating or suggesting a given group cannot be used to reject any of the others under the meaning of 35 USC 102 or 35 USC 103.

Inventions I and any one of groups V-VII are unrelated because each one of the said groups are drawn to methods treating different unrelated diseases and condition using different sets of compounds embraced by different groups already shown to be a separate and distinct inventions.

Inventions I-VII are unrelated because each one of the said groups are drawn to a process of preparation using different unrelated starting materials which produce different sets of compounds, compositions and different methods of use embraced by different groups already shown to be a separate and distinct inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any group is not required any of the others, restriction for examination purposes as indicated is proper.

Claims 22-30, 33, 34, 38-49, 52-53 and 57-61 are linking claims and will be searched too the extent they read on the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability

including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


A telephone call was made to Dale Rieger on 3/4/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond Covington
Examiner
Art Unit 1625


Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600